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EXAMINER

AFREMOVA, VERA

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 09/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/031,952

Applicant(s)

GOMES SANCHES ET AL.

Examiner

Vera Afremova

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2002 and 08 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Claims 1-22 are pending and under examination.

#### ***Claim Objections***

Claims 1-22 are objected to because of the following informalities: first independent claims (claim 1 and 14) should start with article “A” and the following dependent claims should start with “The”. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

##### ***Indefinite***

Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered indefinite by the phrases “characterized to be dispensed as dry powder” and “besides having” because it is uncertain what components are required in the presently claimed composition such as “a bioinsecticide formulation”. The phrase “to be dispensed as dry powder” encompasses an intentional use at the “application area”/site rather than a requirement for the claimed composition to be in a form of powder. The phrase “besides claimed composition or they would be added during process of application of bacterial toxins.

Claim 2 is rendered indefinite by improper use of the abbreviated term “Bti entomotoxine” Abbreviation in the first instance of claims (in claim 1) should be explained upon with the abbreviation indicated in parentheses. The abbreviations can be used thereafter. It is uncertain whether entomotoxin and spores of the claim 2 are required to be made in a form of

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bacterial biomass of the species *Bacillus thuringiensis var. israelensis* or they have some basic characteristics associated with these or similar entomotoxins and spores.

Claim 10 is rendered indefinite by the phrases “characterized to be dispensed as tablet” because it is uncertain whether the tablet composition is claimed or not. The phrase “to be dispensed as tablet” encompasses an intentional use rather than a requirement. It is uncertain whether additional agents are used in a tablet composition or they are intended for diluting, neutralizing the tablet preparation at the site of application.

Claim 14 and depending claims are rendered indefinite by the use of passive voice because it is uncertain what active steps are required in the method of making “a bioinsecticide formulation”. Please, use phrases such as, for example: culturing or carrying fermentation, recovering (specification page 16) and etc.

Claim 15 recites the limitation “the fermentation medium” in the process of making. There is insufficient antecedent basis for this limitation in the claim 14 since it recites only “a suitable growth medium”.

In claim 16 it is uncertain what component is encompassed by the term “amino-fertile” in the lack of definitions.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-4, 6, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 000 235 875.

Claims are directed to a bioinsecticide formulation comprising entomotoxins obtained from *Bacillus thuringiensis var. israelensis* with toxical activity 500-1500 ITU/mg dry powder and additives. The composition appears to be in a form of power or tablet. Some claims are further drawn to the use of entomotoxins in a form of biomass or spores of *Bacillus thuringiensis var. israelensis*. Some claims are further drawn to the use of additives such as chemical dryers, dispersing agents, agglutinant/humectants agents, neutralizing/diluent agents, lubricant agents. Some claims are further drawn to the use of chemical dryers including clay, silica, calcinated silica, diatomite and bentonite at about 0.1-10%, to the use of dispersing agents including cellulose, agglutinant/humectant agents, neutralizing/diluent agents, lubricant agents.

EP 000 235 875 discloses a bioinsecticide formulation comprising entomotoxins obtained from *Bacillus thuringiensis var. israelensis* with toxical activity 1000 ITU/mg tablet (page 16) or 600 ITU/mg granulated dry powder (page 18) and various additives. The cited patent encompasses the use of active ingredients of entomotoxins in a form of toxical biomass or spores of *Bacillus thuringiensis var. israelensis* (page 15, last line). The additives (for example: see page 16 or 18) include chemical dryers such as clay and/or silica at amounts 2% or 5%; dispersing agents such as cellulose at amount 9% or 5%; neutralizing/diluent agents such as kaolin or china clay at amount 2% or microcrystalline cellulose at amount 9% or 5%, lubricant agents such as PEG 400 at amount 15%.

Thus, the cited patent anticipates the claimed invention.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 000 235 875 taken with US 5,747,025, US 5,560,909 and US 5,273,746.

Claims 1-4, 6, 10 and 11 as explained above. Some claims are further drawn to the use of additional inert components in the BTI containing formulation including diatomaceous earth, calcium carbonate, lactose, sodium laurylsulfate, sunlight protectors, etc.

EP 000 235 875 discloses a bioinsecticide formulation comprising an active ingredient that is entomotoxins obtained from *Bacillus thuringiensis var. israelensis* and various additives including china clay, silica, microcrystalline cellulose, PEG 400 at amounts within the presently claimed concentrations. Although the cited patent EP 000 235 875 is missing particular disclosure related to the use of some particular additives, the other cited references demonstrate that all presently claimed components have been known, suggested and/or used in the insecticidal compositions with the BTI toxins.

For example: US 5,747,025 teaches incorporation of sodium laurylsulfate and kaolin into the Bti toxin containing formulation (col. 6, lines 40-46). US 5,273,746 teaches incorporation of phosphates, talc, lactose the Bti toxin containing formulation (col. 11, lines 19, 43).

US 5,560,909 teaches the use of various additives in the BTI containing formulation effective against *Diptera* insects (col. 5, line 30). The additives comprise UV stabilizers,

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diatomaceous earth, calcium carbonate, lactose, etc. (col.7, lines 1-22). The cited patents teaches that additives and/or fillers are used to improve storage of the Bti containing formulation or to facilitate applications of the Bti formulations in the insect environment (col. 7, lines 10-13).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the inert additives in the Bti toxins containing compositions with a reasonable expectation of success in combating *Diptera* insects because incorporation of additives and/or fillers is used to improve storage and/or to facilitate applications of the Bti formulations in the insect environment and because the presently claimed additives have been known, suggested and/or used in the insecticidal compositions with the BTI toxins as adequately demonstrated by the cited references. The choice of particular additives is considered to be within the purview of an ordinary skill practitioner. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Claims 14-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,747,025 and US 5,273,746 and US 5,560,909 and EP 000 235 875 and US 4,609,550.

Claims are directed to a method of making a Bti containing formulation wherein method comprises steps of culturing *Bacillus thuringiensis var. israelensis* in a fermentation medium with carbon source, nitrogen source and mineral salts, recovering biomass or spores; adding inert carriers and/or dryers, dehydrating and optionally pressing tablets. Some claims are further

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drawn to the use of soy proteins or yeast extracts as nitrogen source, to the use of dextrose or glucose as carbon source and to the use of micronutrients including salts of magnesium, iron, zinc, calcium, etc. in the fermentation medium. Some claims are further drawn to incorporation of particular additives including dispersing, agglutinating and/or protecting agents. Some claims are further drawn to dehydrating at temperature under 30 degree C.

US 5,747,025 discloses that a method of making a Bti containing formulation comprises steps of culturing *Bacillus thuringiensis* in a fermentation medium with carbon source, nitrogen source and mineral salts, recovering biomass or spores, adding inert carriers and/or dryers and dehydrating (examples 1 and 3). The fermentation medium comprises soy proteins or yeast extracts as nitrogen source, dextrose or glucose as carbon source and micronutrients. It is silent about specific micronutrients for culturing bacteria, about specific additives and dehydrating temperature.

However, US 5,273,746 teaches substantially the same method of making insecticidal formulation wherein the bacterial micronutrients include salts of magnesium, iron, zinc, calcium, etc. (col. 12, lines 15-41) in the fermentation medium in the method of making insecticidal formulations based on the bacterial toxins from *Bacillus thuringiensis*.

Furthermore, US 5,560,909 and EP 000 235 875 are relied upon to demonstrate incorporation of various additives into the Bti containing formulations as explained above.

And the cited US 4,609,550 demonstrates the use of low temperature at about 30 degree C in the method of making the Bti containing formulations to avoid toxin inactivation (col.6, lines 18-20).



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Therefore, the presently claimed method of making the Bti containing formulations would have been obvious to one having ordinary skill in the art at the time the claimed invention was made because the prior art teaches substantially similar, if not identical methods comprising identical active steps and substantially similar structural elements. One having ordinary skill would have been motivated to modify the inert additives in the Bti toxins containing compositions with a reasonable expectation of success in combating *Diptera* insects because incorporation of additives and/or fillers is used to improve storage and/or to facilitate applications of the Bti formulations in the insect environment and because the presently claimed additives have been known, suggested and/or used in the insecticidal compositions with the BTI toxins as adequately demonstrated by the cited references. The choice of particular additives is considered to be within the purview of an ordinary skill practitioner. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Vera Afremova

AU 1651

May 27, 2004

A handwritten signature in black ink, appearing to read 'V. Afremova', with a long horizontal flourish extending to the right.

VERA AFREMOVA

PATENT EXAMINER